

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JANSSEN PRODUCTS, L.P. and
JANSSEN SCIENCES IRELAND UC,

Plaintiffs,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 2:16-cv-01032-WHW-CLW

CONSENT JUDGMENT AND ORDER

This action for patent infringement having been brought by Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, “Janssen”) against Defendants Lupin Pharmaceuticals, Inc. and Lupin Limited (collectively, “Lupin”) for alleged infringement of United States Patent Nos. 8,518,987 B2 and 7,126,015 B2 (collectively, the “Patents-in-suit”);

Lupin and Janssen have entered into a Settlement Agreement to settle this action (the “Settlement Agreement”) and a License Agreement (the “License Agreement”) under which Janssen has granted Lupin a license to the Patents-in-suit (the “License”), pursuant to the terms and conditions in the Settlement Agreement and License Agreement;

Janssen currently markets in the United States pursuant to New Drug Application No. 21-976 tablets containing darunavir ethanolate for the treatment of HIV-1 infection, all strengths of which Janssen currently sells under the trade name PREZISTA®;

Lupin Limited filed or caused to be filed Abbreviated New Drug Application No. 202073 (“Lupin’s ANDA”) seeking approval of the U.S. Food and Drug Administration to make,

sell, offer for sale, use and/or import in or for the United States darunavir tablets, 600 mg and 800 mg, as described in Lupin's ANDA (the "Lupin Products");

For purposes of this action only, Lupin acknowledges that the claims of the Patents-in-suit are valid and enforceable solely with respect to the Lupin Products in the United States;

The parties further agree that this Consent Judgment, and any admissions or acknowledgments made herein, may not be relied upon, referenced or used in any way and/or entered into evidence in any litigation or proceeding other than in this action, Civil Action No. 2:16-cv-01032-WHW-CLW, or in a litigation or proceeding arising from a claimed breach of the Settlement Agreement or the License Agreement.

The parties have agreed to terminate this pending action by the entry of this Judgment and Order; and

Janssen and Lupin now consent to this Judgment and Order.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. This Court has jurisdiction over the parties and subject matter of this action.
2. For purposes of this action only, Lupin admits that the claims of the Patents-in-suit are valid and enforceable solely with respect to the manufacture, use, sale, offer for sale and importation of the Lupin Products in the United States.
3. All affirmative defenses, claims and counterclaims, which have been or could have been raised by Janssen and its affiliates against Lupin and its affiliates, or by Lupin and its affiliates against Janssen, in this action solely with respect to the Lupin Products and the Patents-in-suit are hereby dismissed with prejudice.

4. For purposes of this action only, Lupin admits that absent a license from Janssen, the manufacture, importation, use, sale, offer for sale of the Lupin Product in the United States would constitute infringement of the claims of the Patents-in-suit.

5. Lupin and its officers, directors, employees, agents, successors, affiliates and assigns, and all persons or entities acting in concert or participation with them are hereby enjoined from manufacturing, using, offering for sale or selling in the United States, or importing into the United States, the Lupin Products before the “Start Date” provided under the License Agreement between Janssen and Lupin, or as otherwise permitted under the License Agreement.

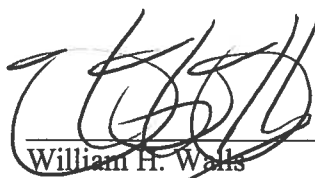
6. The parties waive all rights to appeal from this Judgment and Order.

7. This Consent Judgment, and any admissions or acknowledgements made herein, may not be relied upon, referenced or used in any way and/or entered into evidence in any litigation or proceeding, other than in this action, Civil Action No. 2:16-cv-01032-WHW-CLW, or in a litigation or proceeding arising from a claimed breach of the Settlement Agreement or the License Agreement.

8. This Court shall retain jurisdiction of this action and over the parties for purposes of enforcement of the provisions of this Judgment and Order.

9. Each party is to bear its own costs and attorneys’ fees.

IT IS SO ORDERED this 28 day of June, 2016



William H. Walls

United States Senior District Court Judge

/s/ John E. Flaherty

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